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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,468	03/31/2004	Kit S. Lam	02307W-131410US	6380

20350 7590 03/20/2006

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/20/2006

2 Mo. (Optional) 5/20/2006

Amend/Appeal Due 6/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

RE

Office Action Summary	Application No.	Applicant(s)	
	10/815,468	LAM ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 14-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11-13 and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/27*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 27 December 2005 has been entered.

Status of the Claims

2. Claims 1-30 are currently pending in this application. Claims 9, 10 and 14-28 have been withdrawn from consideration. Claims 29-30 are new. Claims 11-13 are currently amended.

Withdrawn Rejections

3. Previous rejections under 35 USC 112, second paragraph have been withdrawn.

Election/Restrictions

4. Regarding the species election of group A in the restriction requirement issued 17 May 2005, applicant argues that the elected species of group A of an oligosaccharide encompasses agarose and the withdrawal of claim 9 is improper. However, agarose was listed as a separate species of species group A on page 5 of the restriction requirement and therefore should have been elected if agarose was the desired embodiment.

Information Disclosure Statement

5. The reference indicated with a strike-through on the information disclosure statement filed 27 December 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-3, 6, 7, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Li (US 6,704,104).

Regarding claims 1-3 and 7, Li teaches a microarray comprising a support of glass (col. 5, lines 55-58) having a plurality of discrete regions having a biopolymer of oligosaccharides (col. 6, lines 50-66) spotted thereon (col. 13, lines 14-20; col. 16, lines 46-53), wherein attached to the biopolymer in each of the regions is a ligand of sugar that can be the same or different from a ligand in any other of the discrete regions (col. 6, line 65-col. 7, line 12) wherein the biopolymer with ligand is a preformed ligand-modified biopolymer, and wherein the concentration of the ligand in the discrete regions is substantially normalized (amount of light corresponds to the concentration of ligand and is normalized, col. 14, lines 9-18). The biopolymer attached to the ligand is formed prior to sample addition to the sample to the array, and is therefore preformed.

Claim 30 is directed to a microarray made by a specific process and is thus a product by process claim. Product by process limitations do not have patentable weight because it is unclear what product limitations result from the process of making the product. Therefore any product teaching the required product limitations of a product by process claim reads on the product claim. Instant claim 30 requires the following product limitations: a microarray comprising a support having a plurality of discrete regions. As applied to claim 1, above, Li teaches the required product limitation of the microarray and support having a plurality of discrete regions,

the microarray taught by Li encompasses the microarray recited in claim 30. The biopolymer attached to the ligand is formed prior to sample addition to the sample to the array, and is therefore preformed.

With respect to claim 6, Li teaches a biopolymer attached to the support via covalent interactions (col. 7, lines 13-18).

7. Claims 1, 4-6, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al. (US 6,489,159).

Chenchik et al. teach a microarray comprising a support having a plurality of discrete regions having a biopolymer spotted thereon and attached via hydrogen bonding (col. 9, line 54-col. 10, line 6), wherein attached to the biopolymer in each of the regions is a ligand that can be the same or different from a ligand in any other of the discrete regions (ligand attached to biopolymer is a preformed ligand-modified biopolymer, col. 11, lines 39-48; col. different labels distinguishes between different ligands bound in different regions, 12, lines 3-14) wherein the ligand attached to the biopolymer is a preformed ligand-modified biopolymer, and wherein the concentration of the ligand in the discrete regions is substantially normalized (col. 13, lines 4-30).

Claim 30 is directed to a microarray made by a specific process and is thus a product by process claim. Product by process limitations do not have patentable weight because it is unclear what product limitations result from the process of making the product. Therefore any product teaching the required product limitations of a product by process claim reads on the product claim. Instant claim 30 requires the following product limitations: a microarray comprising a support having a plurality of discrete regions. As applied to claim 1, above, Chenchik et al.

teach the required product limitation of the microarray and support having a plurality of discrete regions, the microarray taught by Chenchik et al. encompasses the microarray recited in claim 30.

Claim Rejections - 35 USC § 103

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (US 6,704,104) in view of Bertozzi et al. (US 2003/0073157).

Li, as applied to claim 1, teaches microarray comprising a ligand attached to a biopolymer, but fail to teach attachment via chemoselective ligation.

Bertozzi teach attachment of a ligand to a biopolymer via chemoselective ligation (oligosaccharides are functionalized with chemoselective ligation in order to become suitable coupling partners, par. 63; biopolymer is an oligosaccharide, ligand is peptide scaffold, par. 57-58), in order to provide formation of a better sugar-peptide glycosidic bond.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the microarray of Li, a ligand attached to a biopolymer via chemoselective ligation as taught by Bertozzi et al., in order to control oligosaccharide structure and uniformity and provide better recognition.

9. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al. (US 6,489,159).

Chenchik et al., as applied to claim 1, teach concentration of a ligand in discrete regions substantially normalized and a minimal signal variation desired between discrete reference spots (minimal signal variation corresponds to the amount/concentration of ligand, col. 15, lines 7-10),

but fails to recite a specific value for concentration between discrete regions of varying less than 50%, 20% or 5%.

However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 11-13 are for any particular purpose or solve any stated problem, and the prior art teaches that the amount of ligand between regions should be minimal, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the microarray art.

Response to Arguments

10. Applicant's arguments filed 27 December 2005 have been fully considered but they are not persuasive. Applicant argues that Li discloses normalized fluorescence signals, but does not disclose arrays wherein the ligand concentration is normalized because the arrays disclosed by Li do not normalize ligand concentration on the substrate. Applicant's argument is not persuasive because although the fluorescent signal is normalized, the fluorescent signal is an indication of the concentration of ligand on the substrate. Therefore, by normalizing the fluorescent signal

from the discrete regions on the array, the concentration of the ligand on the substrate is normalized.

11. Applicant also argues that the normalization procedure of Chenchik is to obviate the need to normalize ligand concentration and Chenchik specifically discloses that the ligand concentration is *not* normalized as required by the claims. Applicant's argument is not persuasive because the Chenchik specifically states that the "normalization protocol provides a method for normalizing relative amounts of target compositions". The ligands are normalized by one or more reference ribonucleic acids in a sample. Therefore Chenchik teaches that the concentration of ligands may be normalized by reference nucleic acids. The fact that the ligands of Chenchik do not need to be normalized prior to loading samples on the array does not diminish the reference's teaching of normalization of concentration of ligands.

12. Furthermore, Applicant's limitation of substantially normalizing the concentration of ligands is directed to a method limitation. Applicant's arguments against Li and Chenchik are also directed to the process of normalizing a concentration of ligands on a microarray. The instant claims are directed to a product of a microarray; therefore method limitations are not given patentable weight and only the product limitations of the instant claims must be taught by the reference. Substantially normalizing a concentration of ligands does not appear to provide any further product limitations to the microarray of the instant claims. Therefore, since Li and Chenchik teach the required product limitations of a microarray having a plurality of discrete regions having a biopolymer spotted thereon, wherein attached to the biopolymer is a ligand, as described above, the microarrays of Li and Chenchik would be capable of providing substantial normalization of a concentration of ligands in the discrete region.

13. Regarding the rejection of claim 8 under 35 USC 103(a), applicant argues that Bertozzi fails to teach the concentration of ligands in a discrete region being substantially normalized. However, Bertozzi is not relied upon for this limitation, this limitation is taught by Li and Chenchik as described above.

Conclusion

No claims are allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
Patent Examiner
Art Unit 1641

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
3/13/06

PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete If Known	
Application Number	10/815,468
Filing Date	March 31, 2004
First Named Inventor	Lam, Kit S.
Art Unit	1641
Examiner Name	Melanie J. Yu
Attorney Docket Number	02307W-131410US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No.[1]	Document Number: Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MW	1	US-5,376,372	12-27-94	Okpanyi et al.	
	2	US-5,650,489	07-22-97	Lam, et al.	
	3	US-5,658,802	08-19-97	Hayes, et al.	
	4	US-6,350,572 B1	02-26-02	Bernards, et al.	
	5	US-6,378,527 B1	04-30-02	Hungerford, et al.	
	6	US-6,570,040 B2	05-27-03	Saxon, et al.	
MW	7	US-6,716,642 B1	04-06-04	Wu, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	Melanie Yu	Date Considered	3/10/06

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete If Known	
Application Number	10/815,468
Filing Date	March 31, 2004
First Named Inventor	Lam, Kit S.
Art Unit	1641
Examiner Name	Melanie J. Yu
Attorney Docket Number	02307W-131410US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	8	Cass, T. and F.S. Ligler (Eds.), "Immobilized Biomolecules in Analysis: A Practical Approach", Oxford University Press, 1998	
my	9	Alna, O.H. *et al.*, "Therapeutic cancer targeting peptides." *Biopolymers*, 66(3):184-99 (2002)	
my	10	Christ, S. A. *et al.*, "Quality of assurance considerations for use of the FluorImager SI® and FragmeNT Analysis software." *Electrophoresis*, 21(5):874-88 (2000)	
my	11	Falsey, J.R. *et al.*, "Peptide and small molecule microarray for high throughput cell adhesion and functional assays." *Bioconjug. Chem.*, 12(3):346-53. (2001)	
my	12	Fields, G. B. and R. L. Noble, "Solid phase peptide synthesis utilizing 9-fluorenylmethoxycarbonyl amino acids." *Int J. Pept Protein Res.* 35(3):161-214 (1990)	
my	13	Haab, B. B. *et al.*, "Protein microarrays for highly parallel detection and quantitation of specific proteins and antibodies in complex solutions." *Genome Biol.*, 2(2):research0004.1-0004.13 (2001)	
my	14	Joos, T. O., *et al.*, "A microarray enzyme-linked immunosorbent assay for autoimmune diagnostics." *Electrophoresis*, 21(13):2641-50 (2000)	
my	15	Kaiser, E. et al., "Color test for detection of free terminal amino groups in the solid-phase synthesis of peptides." *Anal. Biochem.*, 34(2):595-98 (1970)	
my	16	Lang, S.H. *et al.*, "Experimental prostate epithelial morphogenesis in response to stroma and three-dimensional matrigel culture." *Cell Growth Differ.* 12(12):631-40 (2001)	
my	17	Lemieux, G. A. and C.R. Bertozzi, "Chemoselective ligation reactions with proteins, oligosaccharides and cells." *Trends Biotechnol.*, 16(12):506-13 (1998)	
my	18	Leung, P. S. *et al.*, "Immunization with a xenobiotic 6-bromohexanoate bovine serum albumin conjugate induces antimitochondrial antibodies." *J. Immunol.*, 170(10):5326-32 (2003)	
my	19	Liu, R. *et al.*, "A novel peptide-based encoding system for "one-bead one-compound" peptidomimetic and small molecule combinatorial libraries." *J. Am. Chem. Soc.*; 124(26):7678-80 (2002)	
my	20	Long, S. A. *et al.*, "Immunoreactivity of organic mimeotopes of the E2 component of pyruvate dehydrogenase: connecting xenobiotics with primary biliary cirrhosis." *J. Immunol.* 167(5):2956-63 (2001)	
my	21	MacBeath, G. and S.L. Schreiber, "Printing proteins as microarrays for high-throughput function determination." *Science*, 289(5485):1760-63 (2000)	
my	22	Migliaccio, C. A. *et al.*, "Monoclonal antibodies to mitochondrial E2 components define autoepitopes in primary biliary cirrhosis." *J. Immunol.*, 161(10):5157-63 (1998)	
my	23	Migliaccio, C., *et al.*, "Heterogeneous response of antimitochondrial autoantibodies and bile duct apical staining monoclonal antibodies to pyruvate dehydrogenase complex E2: the molecule versus the mimic." *Hepatology*, 33(4):792-801 (2001)	
my	24	Miller, J. C., *et al.*, "Antibody microarray profiling of human prostate cancer sera: antibody screening and identification of potential biomarkers." *Proteomics*, 3(1):56-63 (2003)	

Examiner Signature		Date Considered	3/10/06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

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Application Number	10/815,468
Filing Date	March 31, 2004
First Named Inventor	Lam, Kit S.
Art Unit	1641
Examiner Name	Melanie J. Yu
Attorney Docket Number	02307W-131410US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
my	25	Park, S. *et al.*, "The use of one-bead compound combinatorial library method to identify peptide ligands for $\alpha 4\beta 1$ integring receptor in non-Hodgkin's lymphoma." *Lett. Pept. Sci.*, 8:171-78 (2002)	
my	26	Pavlickova, P. *et al.*, "Microarray of recombinant antibodies using a streptavidin sensor surface self-assembled onto a gold layer." *Biotechniques*, 34(1):124-30 (2003)	
my	27	Ponticiello, M.S. *et al.*, "Gelatin-based resorbable sponge as a carrier matrix for human mesenchymal stem cells in cartilage regeneration therapy." *J. Biomed. Mater. Res.*, 52(2):246-55 (2000)	
my	28	Radisic, M. *et al.*, "High-density seeding of myocyte cells for cardiac tissue engineering." *Biotechnol. Bioeng.*, 82(4):403-14. (2003)	
my	29	Robinson, W. H. *et al.*, "Protein microarrays guide tolerizing DNA vaccine treatment of autoimmune encephalomyelitis." *Nat. Biotechnol.*, 21(9):1033-39 (2003)	
my	30	Robinson, W. H. *et al.*, "Autoantigen microarrays for multiplex characterization of autoantibody responses." *Nat. Med.*, 8(3):295-301 (2002)	
my	31	Schweitzer, B. and S.F. Kingsmore, "Measuring proteins on microarrays." *Curr. Opin. Biotechnol.*, 13(1):14-19 (2002)	
my	32	Shao, J. and J.P. Tam, "Unprotected peptides as building blocks for the synthesis of peptide dendrimers with oxime, hydrazone, and thiazolidine linkages." *J. Am. Chem. Soc.*, 117(14); 3893-99 (1995)	
my	33	Shin, I. *et al.*, "Chemoselective ligation of acetylated 1-maleimidosugars to peptides for the preparation of neoglycopeptides." *Bull. Korean Chem. Soc.*; *21(9)*:845-46 (2000)	
my	34	Song, A. *et al.*, "Synthesis of hydrophilic and flexible linkers for peptide derivatization in solid phase." *Bioorg. Med. Chem. Lett.*, 14(1):161-65 (2004)	
my	35	Song, A. *et al.*, "A novel and rapid encoding method based on mass spectrometry for "one-bead-one-compound" small molecule combinatorial libraries" *J. Am. Chem. Soc.*, 125(20); 6180-88 (2003)	
my	36	Wahl, F. and M. Mutter, "Analogues of oxytocin with an oxime bridge using chemoselectively addressable building blocks." *Tetrahedron Letters*, 37(38):6861-64 (1996)	
my	37	Wilson, D.S. and S. Nock, "Recent developments in protein microarray technology." *Angew. Chem. Int. Ed. Engl.*, 42(5):494-500 (2003)	
my	38	Zhu, H. *et al.*, "Analysis of yeast protein kinases using protein chips." *Nat Genet.* 26(3):283-89 (2000)	
my	39	Zhu, H. *et al.*, "Global analysis of protein activities using proteome chips." *Science*, 293(5537):2101-05 (2001)	

Examiner Signature	Melanie Yu	Date Considered	3/10/06

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